REMARKS

The claims remaining in the case are method claims 8-10.

The Examiner has rejected claim 8 under 35 U.S.C., second paragraph, as indefinite for failure to particularly point out and distinctly claim the subject matter which Applicant regards as this invention. The Examiner urges that the recitation "mammalian species" of claim 8 is indefinite, that the recitation "and" is ambiguous since mammals are likely to have either bacterial or viral infections but not both; and finally that the term "thereafter neutralized" in claim 8, line 7, is incomplete and ambiguous because it is not clear whether the method step encompasses neutralizing after the oral dosing or whether it is neutralized and thereafter orally dosed.

Applicants traverse the rejection with respect to the term "mammalian species" and the objection with respect to the term "and". In the context provided in the specification, there is no indefiniteness. The term mammalian species has a recognized understanding in the art and covers such species as porcine, ruminants, poultry, equine, ovine, human, dogs and cats, etc. This is known and common terminology used in this art. With respect to the Examiner's urging that mammals are more likely to have either bacterial or viral infections at any given time but not both at the same time, the claim language does not imply that the animal species has both at the same time but it simply implies, and this is clear from the specification, that the IgG fraction of the present invention is effective against both bacteria and viruses (see Specification at page 5, referencing domestic livestock as an example of the mammalian species and the Specification at page 4, explaining that the fraction is effective against both bacterial and viruses).

With regard to the Examiner's objection that the claim, by using the phrase "thereafter neutralized" is unclear whether it is the fraction used orally after neutralization or whether it is

neutralized after oral use. This definiteness objection has been eliminated by claim rewording making it clear that it is the neutralized material that is used for the oral dosing. This is consistent with the specification at pages 4 and 7, in the example. By this amendment and these remarks, any doubt is clearly removed. Applicant traverses the Examiner's objection raised concerning further details of the neutralizing agent. Commonly sodium hydroxide is the neutralizing agent used for these fractions, but it is not required. What is important is that the neutralization occurs. This is explained at page 4 and page 7 of the specification. There is no basis in the specification, in chemistry or logic in unduly limiting Applicants to a specific neutralizing agent, since what is important is that the neutralization, in fact, occurs, not whether it is, for example, sodium hydroxide or potassium hydroxide.

The 35 U.S.C. § 103 rejection is traversed. The Examiner has rejected the claims over the combination of either Bier '310 and/or Sprotte '731 and Kempf.

The '310 patent brings out that the IgG can be orally fed; however, it states that it needs to "bypass" the stomach to improve success. In other words, the IgG must be whole which is different than the current patent in which the IgG fraction is acid hydrolyzed to a 55,000 MW protein prior to ingestion. A whole IgG molecule would have a MW of approximately 144,000. The dosing would be correct, but the IgG fraction is not the same hydrolyzed, neutralized fraction defined by the claims.

The '731 patent brings out oral feeding with the IgG <u>being whole again</u> and with doses up to 10 g/d, which does go beyond Applicants' 5 g/d. However, the molecule again is whole, not Applicants' hydrolyzed, neutralizing fraction defined by the claims. The difference between the whole molecule and the fraction is remarkable, and the essence of the invention (see the

examples and Fig. 1 (whole protein) and Fig. 2 (treated fraction)). Moreover, Table 1 on page 8 shows the different amino acid profiles.

The Examiner does acknowledge the difference between '310 and '731 from the current patent due to the acid hydrolysis, heat treatment, and neutralization. However, the Kempf reference does not make up for the '310 and '731 patents' deficiencies so an assertion obviousness is not reasonable.

The Kempf reference does teach to decrease the pH, by acid hydrolysis, heating to 37C and neutralizing, with NaOH. What is missing is that the method described by Kempf is to inactivate viruses that are contained or have contaminated the IgG prep that is being processed to produce IVIG. No suggestion is made to use the fraction itself to take advantage of bacterial static or anti-viral properties. Thus, this methodology might be used to safely manufacture IVIG, but not to give antiviral activity by oral administration of the IgG fraction. It simply is virus inactivation by the described methodology but misses the point of use as provided in the claimed method to provide bacterial static and viral static activity. What is surprising and not obvious is that the whole protein concentrate is not anti-microbial until undergoing Applicants' treatment, and then it surprisingly is for the isolated fraction, but only after undergoing the described treatment. Nothing in the art would suggest this.

Overall, the Kempf reference does not relate the IgG fraction to oral u se for virus inactivation, but rather the decrease in pH, heating, and neutralization to virus inactivation within the fraction. Furthermore, the '310 and '731 patents relate to oral feeding of a whole IgG molecule not a protein produced from hydrolyzing it. Therefore what is not obvious is that acid hydrolysis of the IgG fraction to produce a protein that when orally fed does have bacterial static

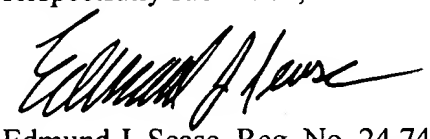
and antiviral activity in the dosed species, while the whole protein concentrate was not bacterial static.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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AMENDMENT — VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

Claim 8 (Amended)

A method of providing bacterial static and viral static activity, comprising:

oral dosing of a mammalian species with an anti-bacterial and antiviral effective amount of a treated, [and] isolated and neutralized IgG fraction which [is] has been treated by acid [hydrolyzed] hydrolysis, [and has been] heated from 15 minutes to 1.0 hour at a temperature of 35°C to 40°C[,] and thereafter neutralized.